

## § 886.1200

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[52 FR 33355, Sept. 2, 1987, as amended at 53 FR 35603, Sept. 14, 1988; 66 FR 38810, July 25, 2001]

### § 886.1200 Optokinetic drum.

(a) *Identification*. An optokinetic drum is a drum-like device covered with alternating white and dark stripes or pictures that can be rotated on its handle. The device is intended to elicit and evaluate nystagmus (involuntary rapid movement of the eyeball) in patients.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[52 FR 33355, Sept. 2, 1987, as amended at 53 FR 35604, Sept. 14, 1988; 66 FR 38810, July 25, 2001]

### § 886.1220 Corneal electrode.

(a) *Identification*. A corneal electrode is an AC-powered device, usually part of a special contact lens, intended to be applied directly to the cornea to provide data showing the changes in electrical potential in the retina after electroretinography (stimulation by light).

(b) *Classification*. Class II.

### § 886.1250 Euthyscope.

(a) *Identification*. A euthyscope is a device that is a modified AC-powered or battery-powered ophthalmoscope (a

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perforated mirror device intended to inspect the interior of the eye) that projects a bright light encompassing an arc of about 30 degrees onto the fundus of the eye. The center of the light bundle is blocked by a black disk covering the fovea (the central depression of the macular retinae where only cones are present and blood vessels are lacking). The device is intended for use in the treatment of amblyopia (dimness of vision without apparent disease of the eye).

(b) *Classification*. Class I for the battery powered device. The battery powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. Class II for the AC-powered device.

[55 FR 48441, Nov. 20, 1990, as amended at 59 FR 63012, Dec. 7, 1994; 66 FR 38810, July 25, 2001]

### § 886.1270 Exophthalmometer.

(a) *Identification*. An exophthalmometer is a device, such as a ruler, gauge, or caliper, intended to measure the degree of exophthalmos (abnormal protrusion of the eyeball).

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

[52 FR 33355, Sept. 2, 1987, as amended at 53 FR 35604, Sept. 14, 1988; 66 FR 38810, July 25, 2001]

### § 886.1290 Fixation device.

(a) *Identification*. A fixation device is an AC-powered device intended for use as a fixation target for the patient during ophthalmological examination. The patient directs his or her gaze so that the visual image of the object falls on the fovea centralis (the center of the macular retina of the eye.)

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

[55 FR 48441, Nov. 20, 1990, as amended at 59 FR 63012, Dec. 7, 1994; 66 FR 38810, July 25, 2001]